



General

Guideline Title

Clinical practice guideline: tinnitus.

Bibliographic Source(s)

Tunkel DE, Bauer CA, Sun GH, Rosenfeld RM, Chandrasekhar SS, Cunningham ER Jr, Archer SM, Blakley BW, Carter JM, Granieri EC, Henry JA, Hollingsworth D, Khan FA, Mitchell S, Monfared A, Newman CW, Omole FS, Phillips CD, Robinson SK, Taw MB, Tyler RS, Waguespack R, Whamond EJ. Clinical practice guideline: tinnitus. *Otolaryngol Head Neck Surg*. 2014 Oct;151(2 Suppl):S1-40. [263 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are defined at the end of the "Major Recommendations" field.

Statement 1. Patient History and Physical Examination

Clinicians should perform a targeted history and physical examination at the initial evaluation of a patient with presumed primary tinnitus to identify conditions that if promptly identified and managed may relieve tinnitus.

Recommendation based on observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To promote a consistent and systematic approach to the initial evaluation of the patient with tinnitus
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: Moderate, as few if any studies specifically investigate the diagnostic yield or effect of history and examination on tinnitus patients
- Benefits: Identify organic, and potentially treatable, underlying causes (e.g., secondary tinnitus); minimize cost and administrative burden through a targeted approach to history and physical examination; streamline care/increase efficiency; improve patient satisfaction; identify

patients with primary tinnitus who may benefit from further management (as outlined in the original guideline document)

- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception by the guideline development group (GDG) that tinnitus sufferers may not receive thorough evaluations from clinicians; further perception that many clinicians are unaware of the optimal targeted history and physical examination to evaluate a patient with tinnitus
- Intentional vagueness: The definition of a "targeted" history and physical examination is elaborated upon in the supporting text.
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 2a. Prompt Audiologic Examination

Clinicians should obtain a comprehensive audiologic examination in patients with tinnitus that is unilateral, associated with hearing difficulties, or persistent (≥ 6 months).

Recommendation based on observational studies, with a preponderance of benefit over risk.

Action Statement Profile

- Quality improvement opportunity: To address potential underutilization of audiologic testing in patients with tinnitus who are likely to have underlying hearing loss and to avoid delay in such diagnosis
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: Moderate, as literature about the effect of prompt audiologic assessment on tinnitus management is scant
- Benefits: Prioritize the need for otolaryngologic evaluation (if not already completed) using audiologic criteria; identify hearing loss, which is frequently associated with tinnitus; characterize the nature of hearing loss (conductive, sensorineural, or mixed; unilateral or bilateral); detect hearing loss that may be unsuspected; initiate workup for serious disease that causes unilateral tinnitus and hearing loss (i.e., vestibular schwannoma [VS])
- Risks, harms, costs: Direct cost of examination; access to testing; time
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The term *prompt* is used to emphasize the importance of ordering a timely test and ensuring that it is done within 4 weeks of assessment, preferably.
- Role of patient preferences: Small; patients may participate in decisions regarding timing of audiogram
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 2b. Routine Audiologic Examination

Clinicians may obtain an initial comprehensive audiologic examination in patients who present with tinnitus (regardless of laterality, duration, or perceived hearing status).

Option based on observational studies, with a balance of benefit and harm.

Action Statement Profile

- Quality improvement opportunities: To promote awareness of hearing loss associated with tinnitus, even in patients who do not have unilateral tinnitus or hearing difficulties, and to emphasize that clinicians do not have to wait 6 months before obtaining an audiogram if deemed appropriate
- Aggregate evidence quality: Grade C, based on observational studies and prevalence of hearing loss in randomized controlled trials (RCTs) of tinnitus therapy
- Level of confidence in the evidence: High
- Benefits: Detect a hearing loss not perceived by the patient—sensorineural hearing loss (SNHL), which is a treatable condition commonly associated with tinnitus; identify patients who may be candidates for sound therapy; identify opportunities for patient counseling/education
- Risks, harms, costs: Direct costs of audiologic testing; detection of minor audiologic abnormalities leading to potentially unnecessary further

testing or referral; inconsistent access to testing

- Benefit-harm assessment: Equilibrium
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making to proceed with audiologic examination
- Exclusions: None
- Policy level: Option
- Differences of opinion: None

Statement 3. Imaging Studies

Clinicians should not obtain imaging studies of the head and neck in patients with tinnitus, specifically to evaluate the tinnitus, unless they have one or more of the following: tinnitus that localizes to 1 ear, pulsatile tinnitus, focal neurological abnormalities, or asymmetric hearing loss.

Strong recommendation (against) based on observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: Avoid overuse of imaging in patients with a low likelihood of any significant benefit from the imaging.
- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: High
- Benefits: Avoid testing with low yield; avoid harms of unnecessary tests (radiation, contrast, cost); avoid test anxiety; avoid detecting subclinical, incidental findings
- Risks, harms, costs: Slight chance of missed diagnosis; relatively high costs and limited access to certain types of imaging studies
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The GDG made this a strong recommendation against, instead of a recommendation against, based on consensus regarding the importance of avoiding low-yield, expensive tests with potential adverse events in patients with tinnitus
- Intentional vagueness: Specific imaging studies are specified in the supporting text, including computerized tomography (CT), computerized tomographic angiography (CTA), magnetic resonance imaging (MRI), and magnetic resonance angiography (MRA)
- Role of patient preferences: None
- Exclusions: None
- Policy level: Strong recommendation (against)
- Differences of opinion: None

Statement 4. Bothersome Tinnitus

Clinicians must distinguish patients with bothersome tinnitus from patients with non-bothersome tinnitus.

Strong recommendation based on inclusion criteria for RCTs on tinnitus treatment, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To identify those patients in need of clinical management and limit unnecessary testing and treatment for others
- Aggregate evidence quality: Grade B, based on inclusion criteria for RCTs on tinnitus treatment
- Level of confidence in evidence: High
- Benefits: Identify patients for further counseling and/or intervention/management; determine effect of tinnitus on health-related quality of life (QOL); identify patients with bothersome tinnitus who may benefit from additional assessment for anxiety and depression; encourage an explicit and systematic assessment of patients to avoid underestimating or trivializing the effect of tinnitus; avoid unnecessary interventions/management of patients with non-bothersome tinnitus
- Risks, harms, costs: Time involved in assessment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: Method of distinguishing bothersome from non-bothersome is not specifically stated. One or more of the validated questionnaires described in the supporting text may be helpful.
- Role of patient preferences: None
- Exclusions: None
- Policy level: Strong recommendation

- Differences of opinion: None

Statement 5. Persistent Tinnitus

Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussions about natural history and follow-up care.

Recommendation based on inclusion criteria in RCTs, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To identify patients with a duration of tinnitus similar to that studied in RCTs of tinnitus treatment; to identify those who may need and benefit from intervention; and to avoid inappropriate interventions for patients with shorter duration tinnitus
- Aggregate evidence quality: Grade B, based on inclusion criteria in RCTs
- Level of confidence in the evidence: Moderate, based on varying tinnitus duration in RCTs, with some including patients with tinnitus of less than 3 months' duration
- Benefits: Identify patients who have a duration of tinnitus similar to the patients included in RCTs, and identify those patients who are most likely to benefit from intervention
- Risks, harms, costs: Defer treatment that may benefit some tinnitus patients who do not have persistent symptoms
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Despite some variation in inclusion criteria for duration of tinnitus used in clinical trials, the GDG felt that 6 months was reasonable time to conclude that the tinnitus would likely persist.
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 6. Education and Counseling

Clinicians should educate patients with persistent, bothersome tinnitus about management strategies.

Recommendation based on studies of the value of education and counseling, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To address potential underutilization of education and counseling by clinicians who manage patients with persistent, bothersome tinnitus. To bring awareness of available management strategies to the patient.
- Aggregate evidence quality: Grade B, based on studies of the value of education and counseling in general, and grade C based on such studies in tinnitus in particular
- Level of confidence in the evidence: High
- Benefits: Improved QOL; increased ability to cope with tinnitus; improved outcomes and patient satisfaction; less health care utilization
- Risks, harms, costs: Direct cost and time
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 7. Hearing Aid Evaluation

Clinicians should recommend a hearing aid evaluation for patients with hearing loss and persistent, bothersome tinnitus.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunities: To promote awareness of the beneficial effect of hearing aids on tinnitus and encourage utilization of this

first-line audiologic intervention for patients with tinnitus, even those who might otherwise be marginal hearing aid candidates

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in the evidence: High
- Benefits: Raise awareness of potential beneficial effects of hearing aids on tinnitus; ensure that patient receives proper guidance regarding benefits and costs of hearing aids; provide patients who have hearing loss with access to information and interventions that may alleviate hearing loss and improve function/QOL
- Risks, harms, costs: Direct cost related to dispensing of a hearing aid
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perceived lack of awareness regarding the ability of hearing aids to improve QOL for patients with tinnitus
- Intentional vagueness: The level of hearing loss is not specified because hearing loss-associated tinnitus may benefit from hearing aids even if the hearing loss is only of a mild degree, or even if there is a more severe unilateral SNHL associated with the tinnitus.
- Role of patient preferences: Patient may accept or decline the recommendation to pursue a hearing aid evaluation

Statement 8. Sound Therapy

Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus.

Option based on RCTs with methodological concerns, with a balance between benefit and harm.

Action Statement Profile

- Quality improvement opportunity: To promote awareness and utilization of sound therapy as a reasonable management option in patients with persistent, bothersome tinnitus
- Aggregate evidence quality: Grade B, based on RCTs with methodological concerns
- Level of confidence in the evidence: Medium, as strength of evidence is low
- Benefits: Access to technology/devices that may relieve tinnitus; improve QOL, sleep, and concentration
- Risks, harms, costs: Consequences of recommending an intervention of uncertain efficacy; promoting false hope; costs associated with sound therapy
- Benefit-harm assessment: Equilibrium
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Significant role in deciding whether to pursue sound therapy and to choose among the available options
- Exclusions: None
- Policy level: Option
- Difference of opinion: One GDG member expressed a difference of opinion about mechanisms of sound therapy, in particular with the concepts of partial and total masking

Statement 9. Cognitive Behavioral Therapy (CBT)

Clinicians should recommend CBT to patients with persistent, bothersome tinnitus.

Recommendation based on RCTs, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To promote awareness and utilization of CBT as an effective management option in patients with persistent, bothersome tinnitus
- Aggregate evidence quality: Grade A, based on multiple systematic reviews of RCTs
- Level of confidence in the evidence: Moderate, based on concerns about methodology and sample size of trials
- Benefits: Treatment of depression and anxiety; improved QOL, tinnitus coping skills, and adherence to other tinnitus treatments
- Risks, harms, costs: Direct cost; time involved (multiple sessions, 1-2 hours each); availability to services may be limited
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation
- Differences in opinion: None

Statement 10. Medical Therapy

Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus.

Recommendation (against) based on systematic reviews and RCTs with methodological concerns, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To decrease the use of medications that may have no benefit and have significant potential side effects, in the management of patients with tinnitus
- Aggregate evidence quality: Grade B, based on RCTs with methodological concerns and systematic reviews demonstrating a low strength of evidence
- Level of confidence in the evidence: Medium regarding the lack of efficacy of medical therapy as a primary treatment for persistent bothersome tinnitus, as several studies with methodological flaws, bias, and lack of power did show some benefit in certain tinnitus outcome measures
- Benefits: Avoid unproven therapy, side effects/adverse events (including tinnitus), and false hope; reduce expense. Avoid use of medications that are not approved for use in geriatric population.
- Risks, harms, costs: Denying some patients benefit
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Although these therapies appear to be beneficial in some studies, the evidence from systematic reviews and RCTs is insufficient to justify routine use in managing tinnitus patients, especially given the known harms, cost of therapy, and potential for some medications (e.g., antidepressants) to worsen tinnitus.
- Intentional vagueness: The term *routine* is used to acknowledge that there may be individual circumstances for which clinicians and patients may wish to pursue therapy.
- Role of patient preferences: Limited; a trial of medication may be administered based on individual circumstances
- Exclusions: Patients with depression, anxiety, or seizure disorders that constitute an indication for pharmacologic therapy independent of tinnitus
- Policy level: Recommendation (against)
- Differences in opinion: None

Statement 11. Dietary Supplements

Clinicians should not recommend Ginkgo biloba, melatonin, zinc, or other dietary supplements for treating patients with persistent, bothersome tinnitus.

Recommendation (against) based on RCTs and systematic reviews with methodological concerns, with a preponderance of benefit over harm.

Action Statement Profile

- Quality improvement opportunity: To avoid use of commonly available supplements that have no proven efficacy and pose potential harm, in the management of patients with tinnitus
- Aggregate evidence quality: Grade C, RCTs and systematic reviews with extreme heterogeneity; most of the RCTs raise significant concerns regarding methodology and subject selection
- Level of confidence in the evidence: High confidence regarding potential harm and adverse effects related to these agents, particularly in the elderly population; low confidence in benefits due to methodological concerns and study quality and ability to generalize results to patients with persistent, primary tinnitus
- Benefits: Avoid unproven therapy, side effects/adverse events (including tinnitus), and false hope; reduce expense
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: There is concern regarding the actual content and dosage of proposed active agents in these preparations, as they are currently packaged over the counter. Many of these supplements, not under the regulation of the U.S. Food and Drug Administration (FDA), have varying amounts of the active agent. The GDG was concerned over the widespread availability for easy purchase of these agents without considering potential drug interactions and adverse events.
- Intentional vagueness: The term *dietary supplements* is used to generalize nutritional and herbal supplements promoted as remedies for

tinnitus.

- Role of patient preferences: Limited role
- Exclusions: None
- Policy level: Recommendation (against)
- Differences in opinion: The majority of the GDG felt that there was a clear predominance of harm over benefit; a minority felt that there was equilibrium. None of the group perceived a preponderance of benefit over harm

Statement 12. Acupuncture

No recommendation can be made regarding the effect of acupuncture in patients with persistent bothersome tinnitus.

No recommendation based on poor quality trials, no benefit, and minimal harm.

Action Statement Profile

- Quality improvement opportunity: Limited, to educate patients and providers about the controversies regarding the use of acupuncture for tinnitus
- Aggregate evidence quality: Grade C, based on inconclusive RCTs and the presence of costs and potential harm with no established benefit with the use of acupuncture for tinnitus
- Level of confidence in the evidence: Low regarding benefit because of heterogeneity and methodological flaws in the RCTs; high regarding harm or cost, with the understanding that serious harm from acupuncture is rare.
- Benefits: No direct benefits of no recommendation
- Risks, harms, costs: Cost of acupuncture therapy, time required for therapy, and potential delay in instituting sound therapy or hearing aids
- Benefit-harm assessment: Unknown
- Value judgments: The poor quality of the data and the limited potential for harm from acupuncture kept the GDG from making a recommendation about acupuncture.
- Intentional vagueness: None
- Role of patient preferences: Significant role for shared decision making; patients may wish to try acupuncture based on circumstances
- Exclusions: None
- Policy level: No recommendation
- Differences in opinion: Minor: The GDG was divided between making no recommendation and making a recommendation against the use of acupuncture.

Statement 13. Transcranial Magnetic Stimulation (TMS)

Clinicians should not recommend TMS for the treatment of patients with persistent, bothersome tinnitus.

Recommendation (against) based on inconclusive RCTs.

Action Statement Profile

- Quality improvement opportunity: To avoid use of a therapy that has inconclusive efficacy and poses potential financial and physical harm, in the management of patients with tinnitus
- Aggregate evidence quality: Grade B, based on inconclusive RCTs and systematic reviews that show low strength of evidence
- Level of confidence in the evidence: High regarding the absence of a long-term (>6 months) benefit of TMS; moderate regarding the absence of a short term benefit, since a minority of trials demonstrated transient beneficial outcomes, and strength of this evidence is low
- Benefits: Avoid unproven therapy, side effects/adverse events, and false hope; reduce expense
- Risks, harms, costs: Denying some patients benefit
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exclusions: Patients with depression or other neurological conditions for which TMS is indicated
- Policy level: Recommendation (against)
- Differences in opinion: None

Definitions:

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnosis	Evidence Quality for Treatment and Harm
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). [*] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). [*] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) [*] or that well-done studies (grade A, B, or C) [*] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (grade D) [*] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

^{*}See Evidence Quality for Grades of Evidence above for definitions of evidence grades.

Clinical Algorithm(s)

An algorithm titled "Algorithm of Guideline Key Action Statements" is provided in the original guideline document.

Scope

Disease/Condition(s)

Tinnitus

Note: This guideline excludes patients with pulsatile tinnitus, or tinnitus related to complex auditory hallucinations or hallucinations related to psychosis or epilepsy.

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Otolaryngology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide evidence-based recommendations for clinicians managing patients with tinnitus
- To provide clinicians with a logical framework to improve patient care and mitigate the personal and social effects of persistent, bothersome tinnitus
- To discuss the evaluation of patients with tinnitus, including selection and timing of diagnostic testing and specialty referral to identify potential underlying treatable pathology
- To provide recommendations to guide the evaluation and measurement of the effect of tinnitus and to determine the most appropriate interventions to improve symptoms and quality of life for tinnitus sufferers

Target Population

Adults (18 years and older) with primary tinnitus that is persistent and bothersome

Interventions and Practices Considered

Diagnosis/Evaluation

1. Patient history and physical examination
2. Comprehensive audiologic examination
3. Imaging studies (only if indicated)
4. Identification of patients with bothersome tinnitus vs. patients with non-bothersome tinnitus
5. Identification of patients with recent onset bothersome tinnitus vs. patients with persistent symptoms ≥ 6 months

Treatment/Management

1. Education and counseling of patients with persistent, bothersome tinnitus about management strategies
2. Hearing aid evaluation
3. Sound therapy
4. Cognitive behavioral therapy (CBT)

Note: The following interventions were considered but no recommendation was made or were recommended against:

Medical therapy (antidepressants, anticonvulsants, anxiolytics and intratympanic medication)
Dietary supplements (e.g., Ginkgo biloba, melatonin, zinc)
Acupuncture
Transcranial magnetic stimulation (TMS)

Major Outcomes Considered

- Reduction of cost, complications, and adverse events associated with tinnitus
- Quality of life (QOL)
- Patient satisfaction

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An information specialist conducted 2 literature searches using a validated filter strategy. The search terms used were tinnitus [MeSH], tinnit*, ear and (ring* or buzz* or roar* or click* or puls*). These search terms were used to capture all evidence on the population, incorporating all relevant treatments and outcomes.

The initial literature search identified clinical practice guidelines, systematic reviews, and meta-analyses related to tinnitus in adults published up to March 12, 2013. The search was performed in multiple databases including MEDLINE, EMBASE, the National Guideline Clearinghouse (NGC) (www.guideline.gov) , The Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database, Agency for Healthcare Research and Quality (AHRQ), PubMed, Guidelines International Network, Health Services/Technology Assessment Tools, CMA InfoBase, NHS Evidence, National Institute for Health and Care Excellence, Scottish Intercollegiate Guidelines Network, New Zealand Guidelines Group, Australian National Health and Medical Research Council, and the TRIP database.

The initial search yielded 271 potential guidelines and 621 potential systematic reviews or meta-analyses. After removing duplicates, articles not related to tinnitus, those not indicating or explicitly stating a systematic review methodology, and non-English language articles, 8 guidelines and 71 systematic reviews or meta-analyses remained. After review by authors and guideline development group (GDG) leadership, 29 systematic reviews were ultimately used in the final publication.

A second literature search identified randomized controlled trials (RCTs) published up to April 1, 2013. The following databases were used: MEDLINE, EMBASE, CINAHL, and CENTRAL. The search identified 2046 potential RCTs. After removing duplicates, non-English language articles, animal model studies, and nonrandomized trials, 232 RCTs remained.

Final results of both literature searches were distributed to panel members. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through August 2013.

Number of Source Documents

- Initial search: 29 systematic reviews
- Second literature search: 232 randomized controlled trials

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnosis	Evidence Quality for Treatment and Harm
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields. As much of the guideline dealt with evidence relating to diagnostic tests, the definitions for Evidence Quality for Grades of Evidence (see the "Rating Scheme for the Strength of the Evidence" field) was adapted to include current recommendations from the Oxford Centre for Evidence-Based Medicine.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the third edition of *Clinical Practice Guideline Development Manual: A Quality-Driven Approach for Translating Evidence into Action*. Members of the guideline development group (GDG), include pediatric and adult otolaryngologists, otologists/neurotologists, a geriatrician, a behavioral neuroscientist, a neurologist, an audiologist, a family physician, a radiologist, a psychiatrist, an internist, a psychoacoustician, an advanced nurse practitioner, a resident physician, and consumer advocates.

Toward the end of the clinical practice guideline (CPG) development process, an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review (CER) on the evaluation and treatment of tinnitus was published in August 2013. The evidence reviews in this document were studied by the GDG, analyzed, and integrated into the recommendations of this CPG where appropriate and relevant.

In a series of conference calls, the working group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in November 2013, the group met twice, with in-person meetings following the format previously described, using electronic decision support (BRIDGE-Wiz, Yale Center for Medical Informatics, New Haven, Connecticut, USA) software to facilitate creating actionable recommendations and evidence profiles. Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting CPGs.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in November 2013 and modified an advanced draft of the guideline.

The recommendations contained in the guideline are based on the best available data published through April 2013. Where data were lacking, a combination of clinical experience and expert consensus was used.

Rating Scheme for the Strength of the Recommendations

Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). [*] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). [*] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) [*] or that well-done studies (grade A, B, or C) [*] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (grade D) [*] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published

Statement	Definition	evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of the Evidence" field for definitions of evidence grades.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final guideline draft underwent extensive external peer review, including a period for open public comment. All comments received were compiled and reviewed by the panel's chair, and a modified version of the guideline was distributed and approved by the guideline development panel.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations contained in the guideline are based on the best available data published through April 2013. Where data were lacking, a combination of clinical experience and expert consensus was used.

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

By focusing on opportunities for quality improvement, the guideline should improve diagnostic accuracy, facilitate prompt intervention, decrease inappropriate variations in management, reduce unnecessary tests and imaging procedures, and improve outcomes and satisfaction for affected patients.

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- The harm of routine audiologic examination is the detection of minor audiologic abnormalities leading to potentially unnecessary further testing or referral.
- Sound therapy can have consequences of recommending an intervention of uncertain efficacy and promoting false hope.

Contraindications

Contraindications

Magnetic resonance (MR) has its own unique set of potential contraindications and warnings. Some patients cannot tolerate the confinement of the MR equipment and long protocol durations. Some implantable medical devices, such as pacemakers, implanted neurostimulators, and so on, may be contraindicated in the MR environment.

Qualifying Statements

Qualifying Statements

- Guidelines are not intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline panel sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.
- This clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing patients with tinnitus. Rather, it is designed to assist clinicians by providing an evidence based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

This clinical practice guideline is published as a supplement to *Otolaryngology-Head and Neck Surgery* to facilitate reference and distribution. A full-text version of the guideline will be accessible, free of charge, at <http://www.entnet.org> [redacted]. In addition, all American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) guidelines are now available via the *Otolaryngology-Head and Neck Surgery* app for smart phones and tablets. The guideline will be presented to AAO-HNSF members as a mini-seminar at the 2014 AAO-HNSF Annual Meeting & OTO EXPO. Existing website content, brochures, and publications by the AAO-HNSF will be updated to reflect the guideline's recommendations. Podcasts will be developed to introduce the recommendations of this guideline to target clinicians. A plain language summary will be developed to help lay persons navigate the recommendations of this guideline, with emphasis on avoiding unproven and potentially harmful tinnitus treatments. In addition, the AAO-HNSF has developed a flow chart for clinicians (see Figure 1 in the original guideline document) to help clinicians understand the key decisions for evaluation and management of tinnitus as well as to demonstrate the appropriate target patients for the recommendations of this clinical practice guideline (CPG).

The guideline development group (GDG) agreed that the action statements likely to generate the most discussion among clinicians are those

recommending against the use of conventional medical therapies and complementary and alternative medicine (CAM) (including dietary supplements). The group recognized the wide use of a variety of medications for tinnitus, as well as a number of available CAM treatments for tinnitus. The quality of available evidence did not support the use of such medications. Suggestions for future study of these agents for tinnitus, with strict methodology, are detailed in the next section.

The GDG also discussed the cost and availability of recommended interventions, such as hearing aid evaluation, sound therapy devices, and cognitive behavioral therapies. These treatments are often excluded from traditional medical insurance coverage, and specialists who can evaluate and recommend these treatments for tinnitus may not be available to the large number of persons with persistent, bothersome tinnitus.

Implementation Tools

Clinical Algorithm

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Tunkel DE, Bauer CA, Sun GH, Rosenfeld RM, Chandrasekhar SS, Cunningham ER Jr, Archer SM, Blakley BW, Carter JM, Granieri EC, Henry JA, Hollingsworth D, Khan FA, Mitchell S, Montfared A, Newman CW, Omole FS, Phillips CD, Robinson SK, Taw MB, Tyler RS, Waguespack R, Whamond EJ. Clinical practice guideline: tinnitus. *Otolaryngol Head Neck Surg*. 2014 Oct;151(2 Suppl):S1-40. [263 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Committee

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) Guideline Development Panel

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with

potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing interests: David E. Tunkel, occasional consultant for Medtronic. Gordon H. Sun, employed by Partnership for Health Analytic Research, LLC and by UCLA Arthur Ashe Student Health & Wellness Center; received research grant from Blue Cross BlueShield of Michigan and an honorarium from BMJ Publishing Group. Sujana S. Chandrasekhar, consultant/advisor for Cochlear Corp and Med El Corp; received clinical research funding from Sonitus; shareholder and board member for Scientific Development & Research, Inc. Eugene R. Cunningham Jr, salaried employee of AAO-HNSF. James A. Henry, received research funding from Starkey Corp, ReSound Corp, and Phonak Corp. Craig W. Newman, research funding from Sanuthera, Inc. C. Douglas Phillips, stock options in Medsolutions. Richard S. Tyler, grants from Cochlear Corp and DSE Healthcare; consultant for SoundCure, Orusmedical, and Micro Transponder. Richard Waguespack, consultant for Blue Cross BlueShield of Alabama and for Speakers Bureau TEVA: Respiratory; research funding for a tinnitus treatment modality study at the University of Alabama at Birmingham.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the [American Academy of Otolaryngology—Head and Neck Surgery Foundation \(AAO-HNSF\) Web site](#)

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Availability of Companion Documents

The following are available:

- Tunkel DE, Bauer CA, Sun GH, Rosenfeld RM, Chandrasekhar SS, Cunningham ER, Archer SM, Blakley BW, Carter JM, Granieri EC, Henry JA, Hollingsworth D, Khan FA, Mitchell S, Monfared A, Newman CW, Omole FS, Phillips CD, Robinson SK, Taw MB, Tyler RS, Waguespack R, Whamond EJ. Clinical practice guideline: tinnitus. Executive summary. *Otolaryngol Head Neck Surg*. 2014 Oct;151(4):533–41. Electronic copies: Available from the [SAGE Journals Online Web site](#) .
- AAO-HNS Clinical Practice Guideline on Tinnitus. Podcast Part 1 and 2. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. Available from the [SAGE Journal Online Web site](#) .
- Research needs: tinnitus. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. Electronic copies: Available from the [American Academy of Otolaryngology—Head and Neck Surgery Foundation \(AAO-HNSF\) Web site](#) .
- Tinnitus guidelines pocket card. 2014. Printed copies: Available for purchase from the [Guideline Central Web site](#) . Digital copies are also available for purchase from the [Guideline Central Web site](#) .
- Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg*. 2013 Jan;148(Suppl 1):S1–55. Electronic copies: Available from the [SAGE Journals Online Web site](#) .

In addition, a slideset is available from the AAO-HNSF by contacting Leslie Caspersen (lcaspersen@entnet.org).

Patient Resources

The following are available:

- Plain language summary: tinnitus. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. 2 p. Electronic copies: Available from the [American Academy of Otolaryngology—Head and Neck Surgery Foundation \(AAO-HNSF\) Web site](#) .
- A representative 8 week cognitive behavioral therapy (CBT) program for tinnitus. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. 1 p. Electronic copies: Available from the [AAO-HNSF Web site](#) .
- Examples of sound therapy device options for tinnitus patients. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. 1 p. Electronic copies: Available from the [AAO-HNSF Web site](#) .
- Patient education discussion points for bothersome tinnitus. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct. 1 p. Electronic copies: Available from the [AAO-HNSF Web site](#) .
- Patient health information: tinnitus. Alexandria (VA): American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). 2014 Oct 14. Electronic copies: Available from the [AAO-HNSF Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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